REMARKS

In this REMARKS section, the following issues are addressed.

1. Examiner Fernandez having not received a later 28 February filing, subsequent to an earlier 27 February filing.

2. The presence of the later 28 February filing in the Fax Unit of the U. S. Patent and Trademark Office.

3. A comparison of amendments to the specification as presented in the earlier 27 February filing and as presented in the later 28 February filing.

4. Additional amendments to the specification as presented in the present SECOND ELECTION OF SPECIES AND AMENDMENT.

5. Additional amendments to the claims as presented in the present SECOND ELECTION OF SPECIES AND AMENDMENT.

6. Election of Species, with Traverse.

1. Examiner Fernandez having not received a later 28 February filing, subsequent to an earlier 27 February filing.

In the Official Action mailed 07/21/2008, Examiner Fernandez indicated that her Restriction Requirement was responsive to communications filed on 03 December 2007 and 27 February 2008.

On 09/08/2008, Applicant's representative Marvin S. Towsend had a telephone conversation with Examiner Fernandez and explained that on 02/28/2008 he had filed an additional communication, entitled SUBSTITUTE AMENDMENT AFTER ELECTION, and that paper was not referred to in the Restriction Requirement.

Examiner Fernandez checked her files, and she did not see the later 28 February filing in her files. Mr. Towsend explained that he has proof of the 02/28/2008 filing in the form of an "Auto-Reply Facsimile Transmission" receipt dated 02/28/2008.

Examiner Fernandez and Mr. Towsend discussed differences between the earlier 02/27/2008 filing and the later 02/28/2008. The claims in both filings were the same.

With respect to amendments to the specification, Mr. Towsend had not, at that time, made a close comparison of the earlier 02/27/2008 filing and the later 02/28/2008 filing with respect to amendments to the specification.

Examiner Fernandez stated that I could contact the Electronic Business Center at 1-866-217-9197 about the missing later 02/28/2008 filing.

Mr. Towsend suggested that her not receiving the later 02/28/2008 filing was an internal U. S. Patent and Trademark Office matter and that perhaps she should check up on the status of the later 02/28/2008 filing. Also, Examiner Fernandez stated that she would contact her supervisor with respect to the

handling of the Restriction Requirement and the missing 02/28/2008 filing.

2. The presence of the later 28 February filing in the Fax Unit of the U. S. Patent and Trademark Office.

On 09/18/2008, Mr. Towsend called the Electronic Business Center and spoke to Mohamed, Agent #38, at approximately 11:40 AM.

Agent Mohamed checked the fax log and told Mr. Towsend that the later 02/28/2008 filing was received by the U. S. Patent and Trademark Office. It was also scanned into an image file. However, it was not forwarded to Examiner Fernandez. Agent Mohamed told Mr. Towsend that he sent an e-mail request to the Fax Unit to have the subject image file of the later 02/28/2008 filing sent to Examiner Fernandez.

3. A comparison of amendments to the specification as presented in the earlier 27 February filing and as presented in the later 28 February filing.

Then, Mr. Towsend made a close comparison of the earlier 02/27/2008 filing with the later 02/28/2008 filing with respect to the specification of the application and took note of a number of differences between the two filings.

Here are differences in amendments to the specification in the earlier 02/27/2008 filing and the later 02/28/2008 filing:

On the one hand, in the EARLIER 02/27/2008 filing, with respect to an amending of the Abstract in the Published Patent Application, there is the following:

An object of the invention is to provide an electroporation method for treating vesicles with exogenous material for insertion of the exogenous material into the vesicles which includes the steps of: a. retaining a suspension of the vesicles and the exogenous material in a treatment volume in a chamber which includes electrodes, wherein the chamber has a geometric factor (cm.sup.-1) defined by the quotient of the electrode gap squared (cm.sup.2) divided by the chamber volume (cm.sup.3), wherein the geometric factor is less than or equal to 0.1 cm.sup.-1, wherein the suspension of the vesicles and the exogenous material is in a medium which is adjusted such that the medium has conductivity in a range spanning 0.001 to 100 θ÷θ±−⊂⊖−±÷θ− milliSiemens, wherein the suspension is enclosed in the chamber during treatment, and h. treating the suspension enclosed in the chamber with one or more pulsed electric fields. With the method, the treatment volume of the suspension is scalable, and the time of treatment of the vesicles in the chamber is substantially uniform.

On the other hand, in the LATER 02/28/2008 filing, with respect to an amending of the originally filed Abstract of the specification there is the following:

An object of the invention is to provide an electroporation method for treating vesicles with exogenous material for insertion of the exogenous material into the vesicles which includes the steps of: a. retaining a suspension of the vesicles and the exogenous material in a treatment volume in a chamber which includes electrodes, wherein the chamber has a geometric factor (cm.sup.-1) defined by the quotient of the electrode gap squared (cm.sup.2) divided by the chamber volume (cm.sup.3), wherein the geometric factor is less than or equal to 0.1 cm.sup.-1, wherein the suspension of the vesicles and the exogenous material is in a medium which is adjusted such that the medium has conductivity in a range spanning 1 microSiemens/cm to 100 milliSiemens/cm 0.01 to 0.1 milliSiemens, wherein the suspension is enclosed in the chamber during treatment, and h. treating the suspension enclosed in the chamber with one or more pulsed electric fields. With the method, the treatment volume of the suspension is scalable, and the time of treatment of the vesicles in the chamber is substantially uniform.

It is noted that the amendments to enumerated paragraph [009] in the Published Patent Application and to the originally filed specification in the paragraph spanning Page 2, lines 24-29, are the SAME.

On the one hand, in the EARLIER 02/27/2008 filing, with respect to an amending of enumerated paragraph [0073] in the Published Patent Application, there is the following:

[0073] To achieve the foregoing and other advantages, the present invention, briefly described, provides a static chamber with large volume to insure all cell are subject to the same electric field intensity and direction and the density of the cells and material are uniform. With this invention any waveform may be used. This invention is a voltage waveform generator connected to an electrode with parallel plates with has low conductivity media, a cell density of 20 million cells per 10 milliliters or less. The invention uses media with conductivity between 10 microSiemens/cm and 100 milliSiemens/cm as shown in FIG. 2 ~~50 mu S/cm and 500 mu S/cm~~. The invention may be used in clinical applications and has a closed sterile chamber into which the cells and large molecules are inserted and removed.

On the other hand, in the LATER 02/28/2008 filing, with respect to an amending of the originally filed specification at the paragraph spanning Page 19, lines 3-15, there is the following:

To achieve the foregoing and other advantages, the present invention, briefly described, provides a static chamber with large volume to insure all cell are subject to the same electric field intensity and direction and the density of the cells and material are uniform. With this invention any waveform may be used. This invention is a voltage waveform generator connected to an electrode with parallel plates with has low conductivity media, a cell density of 20 million cells per 10 milliliters or less. The invention uses media with conductivity between 1 microSiemens/cm and 100 milliSiemens/cm as shown in FIG. 2 ~~50 mu S/cm and 500 mu S/cm~~. The invention may be used in clinical applications and has a closed sterile chamber into which the cells and large molecules are inserted and removed.

On the one hand, in the EARLIER 02/27/2008 filing, with respect to an amending of enumerated paragraph [0075] in the Published Patent Application, there is the following:

[0075] a. retaining a suspension of the vesicles and the exogenous material in a treatment volume in a chamber which

includes electrodes, wherein the chamber has a geometric factor (cm.sup.-1) defined by the quotient of the electrode gap squared (cm.sup.2) divided by the chamber volume (cm.sup.3), wherein the geometric factor is less than or equal to 0.1 cm.sup.-1), wherein the suspension of the vesicles and the exogenous material is in a medium which is adjusted such that the medium has conductivity in a range spanning 0.001 to 100 milliSiemens as shown in FIG.2, wherein the suspension is enclosed in the chamber during treatment, and

On the other hand, in the LATER 02/28/2008 filing, with respect to an amending of the originally filed specification at the paragraph spanning Page 19, lines 20-30, there is the following:

a. retaining a suspension of the vesicles and the exogenous material in a treatment volume in a chamber which includes electrodes, wherein the chamber has a geometric factor (cm.sup.-1) defined by the quotient of the electrode gap squared (cm.sup.2) divided by the chamber volume (cm.sup.3), wherein the geometric factor is less than or equal to 0.1 cm.sup.-1), wherein the suspension of the vesicles and the exogenous material is in a medium which is adjusted such that the medium has conductivity in a range spanning 0.001 milliSiemens/cm to 100 milliSiemens/cm

0.01 to 1.0 milliSiemens as shown in FIG.2, wherein the suspension is enclosed in the chamber during treatment, and

On the one hand, in the EARLIER 02/27/2008 filing, with respect to an amending of enumerated paragraph [0080] in the Published Patent Application, there is the following:

[0080] The vesicles can be living cells, and the medium can be a physiological medium and has a conductivity between 10 micro and 1000 microS/cm 50 and 500 .mu.S/cm as shown in FIG. 2. The number of living cells that are treated in the chamber at one time can be more than 10 million in number. Furthermore, the number of living cells that are treated in the chamber at one time can be more than 20 million in number.

On the other hand, in the LATER 02/28/2008 filing, with respect to an amending of the originally filed specification at the paragraph spanning Page 20, lines 14-20, there is the following:

The vesicles can be living cells, and the medium can be a physiological medium and has a conductivity between 1 microS/cm and 100 milliS/cm 50 and 500 .mu.S/cm as shown in FIG. 2. The number of living cells that are treated in the chamber at one time can be more than 10

million in number. Furthermore, the number of living cells that are treated in the chamber at one time can be more than 20 million in number.

On the one hand, in the EARLIER 02/27/2008 filing, with respect to an amending of enumerated paragraph [0089] in the Published Patent Application, there is the following:

[0089] In accordance with another aspect of the invention, an electroporation apparatus is provided which includes a chamber which has a chamber volume of at least 2 milliliters. A pair of electroporation electrodes are contained within the chamber. An electroporation medium, carrying vesicles in suspension, is contained in the chamber between the electroporation electrodes. The medium has a conductivity between 10 micro and 1000 microS/cm ~~50 and 500 mS/cm~~ as shown in FIG. 2. A source of pulsed voltages is electrically connected to the electroporation electrodes, and means for adding material to the chamber for electroporation treatment therein. Also, means are provided for removing treated material from the chamber.

On the other hand, in the LATER 02/28/2008 filing, with respect to an amending of the originally filed specification at the paragraph spanning from Page 21, line 31 to Page 22, line 6, there is the following:

In accordance with another aspect of the invention, an electroporation apparatus is provided which includes a chamber which has a chamber volume of at least 2 milliliters. A pair of electroporation electrodes are contained within the chamber. An electroporation medium, carrying vesicles in suspension, is contained in the chamber between the electroporation electrodes. The medium has a conductivity between 1 microS/cm and 100 milliS/cm ~~50 and 500 mS/cm~~ as shown in FIG. 2. A source of pulsed voltages is electrically connected to the electroporation electrodes, and means for adding material to the chamber for electroporation treatment therein. Also, means are provided for removing treated material from the chamber.

It is noted that the amendments to enumerated paragraph [108] in the Published Patent Application and to the originally filed specification in the paragraph spanning from Page 25, line 39 to Page 26, line 13, are the SAME.

On the one hand, in the EARLIER 02/27/2008 filing, with respect to an amending of enumerated paragraph [0122] in the Published Patent Application, there is the following:

[0122] A component of the invention is the use of low conductivity medium within a defined range to limit amperage and heat while simultaneously providing enough ions to effectively

electroporate cells. Typically the medium used will have a conductivity between 10 micro and 1000 microS/cm ~~50 mS/cm and 500 mS/cm~~.

On the other hand, in the LATER 02/28/2008 filing, with respect to an amending of the originally filed specification at the paragraph spanning Page 27, lines 32-37, there is the following:

A component of the invention is the use of low conductivity medium within a defined range to limit amperage and heat while simultaneously providing enough ions to effectively electroporate cells. Typically the medium used will have a conductivity between 10 microS/cm and 100 milliS/cm ~~50 mS/cm and 500 mS/cm~~.

It is noted that the amendments to enumerated paragraph [0125] in the Published Patent Application and to the originally filed specification in the paragraph spanning from Page 28, lines 10-24, are the SAME

Since there are some differences between the earlier 27 February filing and the later 28 February filing, it is VERY IMPORTANT THAT THE AMENMENTS TO THE SPECIFICATION IN THE LATER 28 FEBRUARY FILING BE ENTERED INTO THE CASE.

4. Additional amendments to the specification as presented in the present SECOND ELECTION OF SPECIES AND AMENDMENT.

Aside from the amendments to the specification set forth in the later 28 February filing that should be entered, subsequent to entry of those later 28 February filed amendments to the specification, the present SECOND ELECTION OF SPECIES AND AMENDMENT includes further amendments to the specification.

Please enter the present amendments to the specification AFTER entering the amendments to the specification from the later 28 February filing.

It is noted that amendments to the specification in the present SECOND ELECTION OF SPECIES AND AMENDMENT are supported in the original specification.

More specifically, both of the present amendments to the specification in the paragraph spanning Page 19, lines 3-15 and in the paragraph spanning Page 27, lines 24-31 are supported in the original specification in the original specification at the paragraph spanning Page 20, lines 14-20 which states:

"The vesicles can be living cells, and the medium can be a physiological medium and has a conductivity between 50 and 500 μS/cm. The number of living cells that are treated in the chamber at one time can be more than 10 million in number. Furthermore, the number of living cells that are treated in the chamber at one time can be more than 20 million in number. "

5. Additional amendments to the claims as presented in the present SECOND ELECTION OF SPECIES AND AMENDMENT.

Please note that the following claims are currently in the case: 1 to 6, 8, 16, 19 to 22, 24, 25, 28, 29, 31, 35, 38, 39, 42, 43, 44, and 45.

The following claims have been cancelled: Claims 7, 9 to 15, 17, 18, 23, 26, 27, 30, 32 to 34, 36, 37, 40, and 41.

Among the claims that are currently in the case, the following claims are presented herein as originally filed: Claims 2 to 6, 8, 16, 19 to 25, 28, 29, 35, 38, and 39.

Among the claims that are currently in the case, the following claim was presented in the first Preliminary Amendment: Claim 42.

Among the claims that are currently in the case, the following claim is currently amended herein: Claim 31.

Among the claims that are currently in the case, the following claim is newly presented herein: Claim 45.

More specifically, currently amended apparatus claim 31 now includes the following language:

"which includes electrodes, wherein the chamber has a geometric factor (cm^{-1}) defined by the quotient of the electrode gap squared (cm^2) divided by the chamber volume (cm^3), and wherein said geometric factor is less than or equal to 0.1 cm^{-1})"

The quoted language in claim 31 mirrors substantially the same language found in previously amended method claim 1.

New claim 45 presents a limitation that has been deleted from currently amended claim 31.

6. Election of Species, with Traverse

In the Official Action, Examiner Fernandez set forth Group I method claims and Group II apparatus claims.

More specifically, with respect to Group I method claims, Examiner Fernandez requires that a species be selected among method claims as follows:

species (a) for polynucleotides, relating to claim 22; and

species (b) for polypeptides or proteins, relating to claims 24 and 25.

In response to Official Action, the **Applicants hereby ELECT** species (a) for polynucleotides, relating to claim 22, in the Group I method claims.